



**RCT on the Management of Early Pregnancy Failure**  
**INITIAL SCREENING FORM**

**COMPLETE AT VISIT 01**

Site			Patient No.			Letter Code			Visit No.	
									0	1

**A. CHIEF COMPLAINT (within last 24 hours)**

1. Screening Date: \_\_\_\_\_ - \_\_\_\_\_ - 2 0 0 **FM01DT**  
Month Day Year

2. Low abdominal pain within last 24 hours Yes No  
(1 ) (2 ) **BLLAP**

**IF YES, ANSWER ITEMS A TO C.**

A. How long has it been? \_\_\_\_\_ **BLLAPLEN** Days Hours  
(1 ) (2 ) **BALLAPUNT**

B. Characterize the pain Yes No  
1. Crampy (1 ) (2 ) **BALLAPCRP**  
2. Sharp/Stabbing (1 ) (2 ) **BALLAPSHP**  
3. Dull (1 ) (2 ) **BALLAPDUL**  
4. Localized (in one place) (1 ) (2 ) **BLLAPLOC**  
5. Diffuse (all over) (1 ) (2 ) **BLLAPDIF**  
6. Moving around (1 ) (2 ) **BLLAPMOV**

C. Severity of pain (1 ) (2 ) (3 ) **BLLAPSEV**  
Mild Moderate Severe

3. Vaginal bleeding within last 24 hours (1 ) (2 ) **BLVB**  
Yes No

**IF YES, ANSWER ITEMS A TO D.**

A. How long ago did it start? \_\_\_\_\_ **BLVBLEN** (1 ) (2 ) **BLVBLNT**  
Days Hours

B. Current bleeding compared to normal menses  
Spotting (1 ) **BLVBCMP**  
Less than your normal menses (2 )  
Similar to your normal menses (3 )  
Heavier than your normal menses (4 )  
Profuse (soaked 2 maxipads/hour for 2 consecutive hours) (5 ) (INEL)

C. Clot passed? **BLVBCLOT** Yes No Don't Know  
(1 ) (2 ) (3 )

D. Tissue passed? **BLVBTISU** (1 ) (2 ) (3 )

4. Other complaints **BLOTHCMP** (1 ) (2 ) (3 )

If Yes, Specify \_\_\_\_\_ **BLCMP\_SP**

**COMPLETE SCREENING PHYSICAL EXAMINATION, LABORATORY ASSESSMENT AND  
TRANSVAGINAL ULTRASOUND – MEPF FORM 03.**

**B. ELIGIBILITY SUMMARY**

**1. INCLUSION CRITERIA**

	Yes	No
A. Early pregnancy failure	( 1 )	(INEL) <a href="#">INCL_A</a>
B. Willing to accept randomization	( 1 )	(INEL) <a href="#">INCL_B</a>
C. Willing to comply with the study protocol and follow-up visit schedule	( 1 )	(INEL) <a href="#">INCL_C</a>
D. Access to telephone and able to provide detailed contact information	( 1 )	(INEL) <a href="#">INCL_D</a>
E. Adequate venous access for phlebotomy	( 1 )	(INEL) <a href="#">INCL_E</a>

**2. EXCLUSION CRITERIA**

A. Orthostatic hypotension	(INEL) (2 )	<a href="#">EXCL_A</a>
B. Ovarian hyperstimulation syndrome at current pregnancy	(INEL) (2 )	<a href="#">EXCL_B</a>
C. Contraindication to misoprostol use	(INEL) (2 )	<a href="#">EXCL_C</a>
D. Surgical or medical abortion for the current pregnancy prior to enrollment	(INEL) (2 )	<a href="#">EXCL_D</a>
E. Known or suspected ectopic pregnancy	(INEL) (2 )	<a href="#">EXCL_E</a>
F. Known or suspected pelvic infection	(INEL) (2 )	<a href="#">EXCL_F</a>
G. Hemoglobin < 9.5 mg/dL	(INEL) (2 )	<a href="#">EXCL_G</a>
H. Known clotting disorder or use of anticoagulants	(INEL) (2 )	<a href="#">EXCL_H</a>
I. Cardiovascular disease	(INEL) (2 )	<a href="#">EXCL_I</a>
J. Current breast feeding	(INEL) (2 )	<a href="#">EXCL_J</a>
K. Mental conditions or circumstances that are deemed unsuitable for participating in the study	(INEL) (2 )	<a href="#">EXCL_K</a>
L. Karyotyping of fetal tissue is required	(INEL) (2 )	<a href="#">EXCL_L</a>
M. Concurrent participation in any other intervention trial	(INEL) (2 )	<a href="#">EXCL_M</a>
N. Suspected or confirmed endometrial arteriovenous malformation	(INEL) (2 )	<a href="#">EXCL_N</a>
O. Prior enrollment in MEPF Main Study	(INEL) (2 )	<a href="#">EXCL_O</a>

3. **BASED ON ALL EVIDENCE AVAILABLE:**

- A. Best estimate of gestational age \_\_\_\_\_ Weeks **BLESTGA**
- B. Diagnosis
- |                                 |      |                  |                 |
|---------------------------------|------|------------------|-----------------|
| Embryonic/fetal demise          | (1 ) | [Answer Item 3C] | <b>PREGTYPE</b> |
| Anembryonic gestation           | (2 ) | [Answer item 3C] |                 |
| Incomplete spontaneous abortion | (3 ) | [Answer item 3D] |                 |
| Inevitable abortion             | (4 ) | [Answer item 3E] |                 |
| Complete spontaneous abortion   | (5 ) | (INEL)           |                 |
| Threatened spontaneous abortion | (6 ) | (INEL)           |                 |
- C. Criteria of non-viable pregnancy  
Non-viable pregnancy is closed os, no passage of products of conception, and one of the following findings:
- |   | Yes  | No   | N/A  |                 |
|---|------|------|------|-----------------|
| 1. Embryonic pole or crown-rump length between 5mm and 40mm without cardiac activity                | (1 ) | (2 ) | (3 ) | <b>BLUSCARD</b> |
| 2. Gestational sac $\geq$ 16mm in mean diameter and without an embryo                               | (1 ) | (2 ) | (3 ) | <b>BLUSPOLE</b> |
| 3. Gestational sac grows <2 mm over 5 days or < 3mm over 7 days                                     | (1 ) | (2 ) | (3 ) | <b>BLUSGRWT</b> |
| 4. Abnormal rise in serum $\beta$ -hCG level (< 15% increase over two days) with a yolk sac present | (1 ) | (2 ) | (3 ) | <b>BLUSBHCG</b> |
- D. Criteria of incomplete abortion  
Assumed passage of some poc's with the following:
- |  |      |      |      |                 |
|--|------|------|------|-----------------|
| 1. Endometrial tissue (AP) $\geq$ 30 mm; and | (1 ) | (2 ) | (3 ) | <b>INCMFAB1</b> |
| 2. Uterine size less than 13 weeks           | (1 ) | (2 ) | (3 ) | <b>INCMFAB2</b> |
- E. Criteria of inevitable abortion  
Intrauterine pregnancy (an intrauterine gestational sac  $\pm$  yolk sac or embryonic pole) with the following:
- |                               |      |      |      |                |
|-------------------------------|------|------|------|----------------|
| 1. An open os by digital exam | (1 ) | (2 ) | (3 ) | <b>INEVAB1</b> |
| 2. Active bleeding            | (1 ) | (2 ) | (3 ) | <b>INEVAB2</b> |
| 3. Uterine size < 13 weeks    | (1 ) | (2 ) | (3 ) | <b>INEVAB3</b> |
| 4. Sac size < 46 mm           | (1 ) | (2 ) | (3 ) | <b>INEVAB4</b> |
| 5. Crown rump length < 41 mm  | (1 ) | (2 ) | (3 ) | <b>INEVAB5</b> |
4. **HAS THE PATIENT SIGNED INFORMED CONSENT?**
- |      |                |
|------|----------------|
| Yes  | No             |
| (1 ) | (INEL)         |
|      | <b>CONSENT</b> |
5. **IS THIS PATIENT ELIGIBLE FOR THIS TRIAL?**
- |      |             |
|------|-------------|
| (1 ) | (INEL)      |
|      | <b>ELIG</b> |

C. **ADMINISTRATIVE MATTERS**

1. Comments: \_\_\_\_\_ **GEN-CMNT**
2. Person Completing Form: \_\_\_\_\_ **CERT\_SIG** Staff ID Number \_\_\_\_\_ **CERT\_NO**
3. Date form completed: \_\_\_\_\_ **COMPL\_DT** \_\_\_\_\_ - \_\_\_\_\_ - 2 0 0  
Month Day Year